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PATENT

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: ALEXANDER et al.
Appl. No.: 10/766,912
Filed: January 30, 2004
For: PERSONAL CARE COMPOSITIONS WITH
PORTABLE PACKS

L E T T E R

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Date: March 3, 2004

Sir:

Under the provisions of 35 U.S.C. § 119 and 37 C.F.R. § 1.55(a), the applicant(s) hereby claim(s) the right of priority based on the following application(s):

<u>Country</u>	<u>Application No.</u>	<u>Filed</u>
NEW ZEALAND	523 946	January 31, 2003

A certified copy of the above-noted application(s) is(are) attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

YOUNG & THOMPSON

By

Benoît Castel
Benoît Castel, #35,041
745 South 23rd Street, Suite 200
Arlington, Virginia 22202
(703) 521-2297

BC/psf

Attachment

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Complete Specification as filed on 28 January 2004 with an application for Letters Patent number 523946 made by Carl Ernest Alexander and Francis William Grayson.

Dated 4 February 2004.



Neville Harris
Commissioner of Patents, Trade Marks and Designs



Patents Form No. 4.

Patents Act 1953
Provisional Specification.

PORTABLE ORAL HYGIENE COMPOSITIONS

We, Carl Ernest Alexander of Church House, High Halden, Kent TN26 3JB, England, and Francis William Grayson, of 50 Orakei Road, Remuera, Auckland *do hereby declare this invention to be described in the following statement:*

Intellectual Property
Office of NZ

31 JAN 2003

RECEIVED

TITLE **PORTABLE ORAL HYGIENE COMPOSITIONS**

FIELD

This invention relates to oral hygiene compositions; to oral hygiene compositions adapted for use with a portable dispensing device and oral hygiene applicator, and particularly to compositions distributed in single-dose "bead" form for use at any time or place for cleaning the mouth or teeth.

BACKGROUND

There have not been any significant changes in the presentation of compounds usable as tooth cleaning agents for some years. Known tooth-cleaning preparations include the currently successful toothpastes, while dentifrice powders (have largely become obsolete. The dental health of children in particular remains under threat, especially with the availability of sweetened drinks and snack foods in the Western world. A toothpaste commonly contains, in a watery base, a thickener (so that the paste will lie upon the brush before use and in order to avoid settling of components within the tube during storage), an abrasive, a flavour such as peppermint, and a detergent which has surface-active and foaming properties. Toothpaste usually has a white appearance if the abrasive is a mineral powder with a refractive index unlike water. Gel toothpastes may employ a cellulose derivative as a viscosity raising material, and hydrated silica (having a refractive index like that of water (1.33)) as a dentifrice or abrasive, so that they can be extruded on to a brush as a clear or artificially coloured viscous material.

Although ordinary toothpaste as supplied within a deformable container (the tube of toothpaste) is a widely accepted preparation, it can become messy within luggage, either by leakage or rupture of the container, and can build up deposits about the wasbasin and over the cap. There is a potential to spread disease if several people share a toothpaste tube. Ordinary toothpaste is not adapted for carriage in the pocket, ready for use. It is not easy to dispense in simple unit amounts (often children squeeze out far too much) yet issues such as fluoride toxicity (fluoride having a low safety margin for toxicity) suggest that dose monitoring is preferable. Manufacture of a near-solid suspension free of entrapped air and packaged in a low-cost manner is not easy.

A compact toothbrush "kit" including convenient, reliable storage of a few brushings worth of a

toothpaste equivalent would be useful for those people who are often away from home. Apart
30 from tooth cleaning materials such as for travel, other self-administered oral treatments may be
required from time to time; for instance an unpredictable "social emergency" may occur when
about to meet a desirable person or a business contact when aware - or even concerned about
the possibility - that one's mouth is giving off offensive odours.

Recent World Health Organisation figures by country for the incidence of dental caries within
35 children show that several relatively advanced countries have an untoward incidence.

The earlier co-pending application dealt with the principles of non-paste, non-powder oral
hygiene compositions and associated delivery devices. It gave outline specifications for composi-
tions for capsules receiving specific treatments giving them hardened, dried, or coated walls.

PROBLEM TO BE SOLVED

40 To devise improved oral hygiene compositions comprising discrete bead formulations of adapted
compositions which are more convenient to carry about, yet are commercially feasible.

Another problem to be solved is to devise an oral hygiene composition capable of encouraging
children to brush their teeth on a regular basis (even when away from home). An alternative
convenient and child-friendly; indeed, use-encouraging preparation may be of considerable help
45 in terms of paediatric dentistry and minimisation of public health problems in later life.

OBJECT

It is an object of this invention to provide improved dental hygiene compositions or at least to
provide the public with a useful choice.

DEFINITION

50 **BEAD:** We use the term "bead" to describe a soft solid object, a unit dose of a novel dental or
oral composition, at least some versions of which serve the function of a toothpaste.

FOOD GRADE: a non-toxic material which is fully acceptable, particularly with respect to appro-
priate regulations, for oral intake by people.

GEL: "A semi-solid mass, capable of deformation by heat or pressure" 2. "A non-flowing,
55 adhesive mass exhibiting strong cohesive forces having low shear strength". 3. "A colloid in a
more solid form than a sol".

The molecular structure would generally include a framework of long, variably cross-linked
filaments of a gelling agent, supporting other molecules or particles.

GUM: A polymeric substance which, in an appropriate solvent or swelling agent, forms highly
60 viscous dispersions or gels at low dry substance content. (For the present application, water-

soluble gums are of interest. These include: seed gums, tuber and root gums, seaweed extracts, plant extracts, exudate gums, gums made by microbial fermentation, and derived gums).

STANDARD CONDITIONS: An atmosphere of air having a relative humidity of 65% and a temperature of 20 deg Celsius, and a pressure of about 1000 millibars.

65 STATEMENT OF INVENTION

In a first broad aspect the invention provides a capsule-free composition for facilitating the practice of oral or dental hygiene, wherein the composition includes at least one food grade gum or structural gel, the component being present in a concentration capable of conferring rigidity on the composition, so that the composition can be formed into discrete soft solid beads each
70 having a predetermined, substantially permanent shape yet lacking an outer capsule or shell.

Preferably the composition exhibits a softening temperature of more than about 25 degrees Celsius.

More preferably the composition exhibits a softening temperature of more than about 40 degrees Celsius.

75 Preferably the beads are dimensionally stable under standard conditions yet are soft enough to permit being fully disrupted in the mouth during use.

Preferably each bead has a substantially non-sticky surface so that the beads do not tend to stick or merge together.

Preferably the food grade structural gel is a polymer of high molecular weight having an
80 elongated chain similar to, or derived from corresponding molecules extracted from animals or plants including single-celled animals or plants, and algae.

A preferred food grade structural gel is the product widely known as "gelatine"; manufactured from the naturally occurring animal protein collagen.

Another preferred food grade structural gel is selected from the group including substances
85 widely known as "agar" and "carrageenan" as extracted from naturally occurring seaweed, alginic acid and its salts, porphyran, furcellaran, kappa-carrageenan, iota-carrageenan and gamma-carrageenan, or combinations, analogues or derivatives thereof.

Further example food grade structural gels comprise mixtures including one or more of: gelatine, agar or carrageenan as previously described in this section, locust bean gum, guar gum (guaran),
90 locust bean gum, pectin, and starches including corn starch.

Yet further food grade gels include those produced by artificial means whether based on a substrate of a modified natural linear polymer or based on a synthesised polymer.

In a second broad aspect, the invention provides a bead for use in an oral hygiene process, for

● example when cleaning one's teeth; wherein each bead contains (a) a food grade structural gel in
95 sufficient concentration to confer partial rigidity on the composition, together with (b) an effective amount of at least one functional component relevant in a tooth brushing procedure.

Preferably the at least one functional component is selected from a group including: a surface-active compound, water, and a water-retaining compound.

Optionally at least one functional component is selected from a group including:

100 an abrasive substance, a foam stabiliser, a supply of fluoride ions, a supply of calcium ions, a flavouring substance with optional flavour enhancing substance, a colouring agent, preferably corresponding to the flavour, a sweetening agent, a disinfectant, an excipient, and a pH modifier.

One preferred bead composition includes from about 1 to about 8% gelatine (w/w) as the structural gel.

○ 105 More preferably the bead composition includes about 4% gelatine (w/w) as the structural gel.

Another preferred bead composition includes from about 0.1 to about 4% agar (w/w) as the structural gel.

More preferably the bead composition includes about 0.8% agar (w/w) as the structural gel.

Yet another preferred bead composition includes from about 0.1 to about 4% of carrageenan
110 (w/w) as the structural gel.

More preferably the bead composition includes about 0.8% carrageenan (w/w) as the structural gel.

Still another bead composition uses alginic acid or a salt thereof as the structural gel, and optionally that structural gel may be hardened externally by exposure to calcium ions thereby
115 forming a calcium alginate.

○ 120 A preferred composition includes a food-grade structural gel, water, glycerine, a surface-active agent, a foam stabiliser, sodium chloride, a sweetening agent, dicalcium phosphate as an abrasive, and citric acid.

A preferred agar-based bead composition comprises: Boiling water: about 32.1%; Agar: about
120 0.8%; glycerine: about 15%; a surface-active agent (sodium lauryl sulphate; Texapon OC-N): about 1%; a foam stabiliser (coco amido propyl betaine, Synthecol CAB): about 2%; sodium chloride: about 1.5%; a sweetening agent (sodium saccharin): about 0.1%; dicalcium phosphate: about 45%; peppermint oil: about 1%; menthol: about 0.4%; and citric acid: about 0.4%.

Preferably each bead has a weight of from about 0.1 to about 2.5 grams.

125 More preferably each bead has a weight of about 0.5 to 0.75 grams, so that a sufficient amount for a single procedure of brushing the teeth is provided within one bead.

Preferably the composition is shaped and/or coloured and/or flavoured in order to appeal in particular to a child, so that the child is more likely to make voluntary use of the bead for improved oral and dental hygiene.

130 Optionally each bead has a shape adapted to be held by the bristles of a tooth brush.

In a third broad aspect the invention provides a method for making a composition for teeth cleaning purposes according to the invention, the method comprising the steps of

mixing the components into hot water,

cooling the mixture,

135 mixing in the flavouring agent,

and cooling the mixture to below the temperature at which a gel is formed, while the mixture is being formed into beads of a desired shape.

A preferred industrial method for making beads having a composition according to the invention comprises the steps of:

140 1. Add agar, glycerine, surface active agent, foam stabiliser, salt, and sodium saccharin to a jacketed vessel and mix.

2. Add boiling water and mix while raising the temperature to 95-100 deg C.

3. Add dicalcium phosphate and sodium fluorophosphate and mix to a smooth white liquid.

4. Let the temperature drop to 65 deg C while mixing.

145 5. dissolve the menthol in peppermint oil.

6. Add the menthol/peppermint mix and the citric acid when the temperature of the mixture is less than 50 deg C and mix.

7. Pump mixture through a chilled pipe having an internal diameter similar to the desired external diameter of the beads onto a conveyer belt

150 8. Cut the mixture into short lengths; so that the beads themselves are formed.

9. Pack into an airtight container.

Optionally the external surfaces of each are dusted with a food grade powder in order to enhance separation.

Preferably the food grade powder is corn starch.

155 In a fourth broad aspect the invention provides a bead according to the invention as herein described, but adapted for mouth wash usage by virtue of a composition including a food-grade structural gel, and an effective amount of at least one component selected from the group of:

● a non-ionic or anionic disinfectant, such as triclosan.

an anionic surface-active agent such as sodium lauryl sulphate,

160 an oxygen releasing substance (example: magnesium peroxide)

a flavouring substance, optionally with a flavour enhancing substance,

a colouring agent, preferably corresponding to the flavour,

a sweetening agent,

an excipient, and

165 a pH modifier.

an effective amount of the following, sodium fluoride, lidocaine, magnesium peroxide, and excipient.

● Preferably the shape and/or the colour of a bead intended for use as a mouth wash is made to be distinctive from the appearance of a bead intended for use as a toothpaste composition.

170 In a fifth broad aspect the invention provides a complete kit for personal application of dental hygiene, including beads of a dental hygiene composition, dispensing means therefor, and, in addition, brush application means, which kit is provided for sale as a set of items or separately.

Preferably the invention provides means for storing and dispensing beads of a composition as previously described in this section, wherein the means comprises a toothbrush including at least

175 one resealable cavity each capable of storing a plurality of discrete beads, so that the consumable beads and the brush application means for applying the composition to one's teeth are kept together.

● In a related aspect, the toothbrush includes two resealable cavities, so that at least one cavity is available for storage of an oral hygiene commodity other than a dental hygiene composition.

180 In a sixth broad aspect the invention provides a pack for storage of a plurality of beads according to the invention, each held within a compartment along an elongated tape.

Preferably the tape is provided with frangible sections so that compartments can be separated from one another

For example the invention provides a continuous strip of individually wrapped beads, able to be
185 torn off at a requisite number, offered on a complimentary basis or for sale, for dispensary, school or hospital individual use, being that the user can tear open the single portion for single use, the remainder being kept in an hygienic condition until required.

In a related aspect the tape containing beads is made available for personal use.

● In another related aspect the tape containing beads within compartments is placed in a dispenser
190 and dispensed on a compartment-by-compartment basis from the dispenser for personal use.

Preferably the dispensed bead remains sealed within the compartment until removed by the person.

In a related aspect the system for delivery of dental hygiene (including encapsulated beads and application means (such as a toothbrush) is provided as a set of items at a point of sale, in a
195 readily portable format for use anywhere, home, office, holiday etc or a dispensing system for domestic or similar use.

PREFERRED EMBODIMENT

The description of the invention to be provided herein is given purely by way of example and is not to be taken in any way as limiting the scope or extent of the invention.

●
200

DRAWINGS

Fig 1: shows in outline or surface view several shapes for capsules of encapsulated toothpaste
(PRIOR ART)

Fig 2: shows several shapes for beads of an oral composition according to the invention.

Fig 3: shows a tape holding beads, suitable for use with a dispenser.

205 Fig 4: shows a coin-operated dispenser for providing beads to a local population (family, business, institution, hospital, or the public at large).

Fig 5: shows a toothbrush including a container in the handle (storage mode). (PRIOR ART)

Fig 6: shows a toothbrush including a container in the handle (ready for use). (PRIOR ART)

●

INTRODUCTION

210 This invention provides an alternative form of dental hygiene preparation in which a composition broadly similar to that of conventional toothpaste as obtained from a tube but rendered solid by addition of a structural gel is provided within a plurality of individual "single-use" portions, which we prefer to call "beads". "Capsule" is an inappropriate term because oral hygiene compositions according to this invention have no separate containing structure such as a gelatine capsule; the
215 composition is originally the same throughout. The bead walls are made from the same composition and at the same time as the body of the bead. Walls may optionally be dusted during manufacture with a powder, and the surfaces may become a little harder or drier during storage. The periphery may become measurably drier and hence more rigid than the centre after storage. Conveniently each bead weighs about 0.5 grams, about half of which is an abrasive material,
220 providing about the right amount of toothpaste for an average tooth-cleaning procedure. Differing

sizes may be made available for small children, larger children, or adults.

In contrast to our expectations that capsules would be necessary, it has been found that selection of an appropriate gelling agent, added in a sufficient concentration to the other ingredients of the oral hygiene composition allows individual beads to be formed at the time of manufacture. The beads may be described as "soft solids". Although they retain their shapes during extended periods of storage, they are completely broken apart by the forces involved in brushing teeth, pressing, or biting. The beads stay separate during storage and there is substantially no syneresis (exudation) during substantial periods of storage. Prior-art gel toothpastes are actually viscous liquids, not solids, and include enough cellulose derivative gel to be held on a toothbrush after a "dose" is ejected from a tube of toothpaste ready for immediate use.

It is possible to make beads in almost any consistency, flavour, colour, shape, or size, and some prior-art examples of shapes 101, 104, 105, 106, 107, 108 and 109 (from our co-pending application PCT/IB01/02772) are shown in Fig 1. Fig 2 shows more prosaic shapes; a cylinder 201 is easy to extrude, while the surface-modified and "D" section (202) versions sit better on the bristles 203 of a brush 204 ready for use. A flat sided pellet 205 with or without indentured surfaces 206 may be more easily held on the bristles of a brush. Another option is to manufacture the beads in a discoidal shape 207 (with or without indentured surfaces 208) to fit the head of a rotating electric toothbrush.

Fig 3 illustrates a tape 300 holding a plurality of individual beads 302 each in a perforation-bounded (303) rectangle of paper 301, suitable for rolling into a reel and dispensing beads, one by one, from a machine (Fig 4). Section A-A is shown in Fig 3b, and a tearable opening means is shown at 305 in the magnified single rectangle 306 (Fig 3c). A film of shrink-wrap material 304 or the like protects each bead until used. Fig 4 simply shows a wall-mounted dispensing machine having outlets 401, 402, and 403 for a variety of beads, each one selectable (in this example) by placing a coin or token in a related slot (404, 405, or 406). A machine of this type can be modified to also offer tooth brushes, with or without included beads. Figs 5 and 6 show a portable toothbrush (shaft 502) from the above prior art document, beads (e.g. 106) in a compartment within a handle, sealed by a lid 506. A protective cover 501 (see fig 5) can be used as a handle extension when brushing - as per fig 6. A star-shaped bead 104 is shown on the bristles 503, ready for use.

Providing a variety of visually different yet functionally similar beads gives a child a choice that is intended to promote the frequency of voluntary cleaning of teeth (providing a choice being a well-known subterfuge when causing children to comply with their parents' requests). Beads and their dispensers can be made far more attractive to children. An intention is to make the process of cleaning teeth so attractive to children that it becomes a pleasure.

It will be appreciated by a reader skilled in the art that the scope of this invention extends to all forms of toothpaste when modified by addition of a gel into a storage-compatible bead-like form particularly wherein each individual bead is suitable for a single use. Other oral compositions such as breath fresheners and oral antiseptics are included in the scope.

260 Providing the oral/dental hygiene composition as separate, semi-rigid and non-sticky lumps (the beads) gives a free-flowing material, no longer needing the special containment provided by a toothpaste tube, so that a person can decant some beads from a large container into a small container as for example when travelling. (The "small container" may for example be constructed within a toothbrush handle). The preferred beads have a homogenous structure without a
265 significantly differentiated wall or capsule, so that no waste results. A further point is that the waste disposal problem caused by discarded toothpaste tubes in particular is considerably reduced.

Some specific formulations provided herein employ gelatine as gel providing a soft framework; others employ agar for the same purpose. Another group includes substances extracted from
270 naturally occurring seaweed. In general these have a structure based on polysaccharide chains including polymers of D-mannuronic acid or L-guluronic acid (example: alginic acid and its salts), or sulphated galactans (examples include agar, porphyran, furcellaran, and kappa-, iota- and gamma-carrageenan), or combinations, analogues or derivatives thereof. (At this time, carrageenan has not been specifically tested although the properties of the various carrageenans
275 appear like those of agar). Some of a number of formulations have been tested and are now given in detail. The reader skilled in the art will realise that oral hygiene formulations involving other amounts, variations, or mixtures of gels or analogous molecules, modified forms thereof, and other long-chain molecules capable of conferring on a mixture physical properties analogous to those of agar, gelatine, and the like will lie within the scope of the invention.

280 In use, one or perhaps more beads are selected for use, removed from a container or dispenser and mechanically disrupted within the mouth perhaps by finger pressure, pressing the bead on to the bristles of a brush, or against the teeth, or by being bitten. After that step, a conventional toothbrush (which may be electric) is used in the normal manner.

EXAMPLE 1

Component	% w/w
Hot water	q. s.
Gelatine	4
Glycerine	20
Texapon OC-N	1
Synthecol CAB	2
V41 Sodium chloride	1.3
Sodium (Na) saccharin	0.1

Component	% w/w
Dicalcium phosphate dihydrate	50
Sodium fluorophosphate	0.7
Sodium dihydrogen citrate	0.5
(a) version: Menthol	0.1- 0.2
(a) version: Peppermint oil	0.6
(b) version: Orange oil	0.7
(b) version Tartrazine 1%	0.1
(c) version: Strawberry flavour	0.7
(c) version Ponceau Red 0.2%	0.1
	100.00%

285 Notes on components.

Gelatine is the solidifying gel in this Example. Gelatine is based on a reconstituted collagen extract and is widely available as a foodstuff. The remaining components are generally found in any toothpaste.

Glycerine (glycerol) serves as a hygroscopic water-retaining agent.

290 Texapon (R) OC-N (Henkel NZ Ltd) is a commercial brand of sodium lauryl sulphate (an anionic surface-active agent) having minimal taste or flavour of its own.

Synthecol CAB (coco amido propyl betaine; Chemcolour Industries (NZ) Ltd) is a commercial brand of a foam stabiliser/thickener having minimal taste or flavour of its own. Supplied as a liquid having 30% active concentration.

295 V41 salt is a vacuum-dried sodium chloride (Dominion Salt, NZ).

Sodium saccharin (Bronson & Jacobs) is a sweetening agent.

Dicalcium phosphate dihydrate (Victor DF) (Rhodia Food, Cranbury NJ USA) is a substantially insoluble salt, used as an dentifrice (abrasive). The fineness of the powder is such that 99.5% will pass through a 325 mesh.

300 Sodium monofluorophosphate (Lever Rexona, Jackson St Petone NZ) is a source of fluoride ions generally used for local hardening of the enamel. It is preferred over sodium fluoride for safety reasons in particular.

Calcium glycerophosphate (1-4 %) is optionally added; it may act as a reservoir of calcium ions and/or as a "buffer" for fluoride ions.

305 Preferred dyes are (a) food-grade and (b) fade resistant, as from sunlight. A tendency we have noted (when beads of different colours are stored together) for soluble dyes to diffuse into adjacent beads and blending with other colours suggests that adsorbing a colour onto the abrasive particles may be a preferable colouring method. A laking pigment (adsorbed onto a substrate such as aluminium oxide powder) may be preferred.

31 Manufacture:

1. Add gelatine, glycerine, Texapon OC-N, Synthecol CAB, salt, and Na saccharin to a jacketed vessel and mix.
2. Add hot water and mix while holding the temperature.
3. Add Dicalcium phosphate and Na fluorophosphate and mix to a smooth white liquid.
- 315 4. Let the temperature drop to about 65 deg C while mixing.
5. Dissolve the menthol in peppermint oil. (or flavour/ colour options (b) and (c) if selected).
6. Add the flavour/colour option mix and the citric acid when temperature is less than 50 deg C and mix.
7. Pump mixture through a chilled 6.5 mm ID pipe onto a conveyer belt and cut into approximately 10 mm lengths. (200 items).
- 320 8. Dust each bead lightly with corn starch.
9. Pack into an airtight container.

RESULTS:

Beads were opaque cylinders, white or having pastel colours if a dye was added.

- 325 These results refer to peppermint/menthol versions. In terms of shelf life and related storage. We found that gelatine-based beads were not able to hold their shape well, especially at raised temperatures in accordance with the known properties of gels based on gelatine.

Beads were placed in direct sunlight on a window sill for 3 hours. The outside shell crusted marginally but remained pliable and usable. The inventor left beads exposed in a steamy
330 bathroom for 3 hours. They retained their shape and did not get tacky or stuck together and remained usable.

Samples according to Example 1 were placed in direct sunlight, outside in a clear plastic bag. They melted and lost shape under temperatures exceeding 30 deg C. They were usable when cooled but had lost their shape. Samples placed in a plastic bag and left on the back floor (in
335 shadow) of a black BMW car in direct sunlight, at a temperature of at least 28 deg C softened but did not lose shape. They could be handled carefully and, not becoming tacky, could be used. Under adverse conditions it may be difficult to extract an individual bead from storage in a canister for use. This version would probably fail storage specifications, because temperatures of over 30 deg C within a person's pocket could result in loss of shape and integrity. To raise the
340 concentration of gelatine beyond about 5% renders the beads less attractive to users in terms of "mouth feel" and less disintegration during use. There may be other ways to overcome the low-temperature melting problem, such as the use of a gelatine extracted under different conditions,

or use of a mixture including another gelling substance. The glycerol (glycerine) has a hygroscopic property and serves as a water retention agent. At the preferred concentration of glycerol, there was some reversible tendency for the periphery of each bead to lose water and harden slightly when in an atmosphere of low humidity.

EXAMPLE 2

<i>Component</i>	<i>% w/w</i>
Hot water	q. s.
Gelatine superfine	5
Glycerine BP	25
Sodium bicarbonate	0.5
Sodium chloride (V41 salt)	1.3
Na saccharin	0.1
Dicalcium phosphate dihydrate	50
Na fluorophosphate	0.2
Sodium dihydrogen citrate	0.5
Peppermint oil	0.5
	100.00%

Notes: This example varied the gelatine in order to provide a more rigid bead.

EXAMPLE 3

<i>Component</i>	<i>% w/w</i>
Hot water	q. s.
Gelatine	4
Glycerine	20
Texapon OC-N	1
Synthecol CAB	2
V41 salt	1.3
Na Saccharin	0.1
Hydrated silica	30 approx
Na Fluorophosphate	0.7
Sodium dihydrogen citrate	0.5
Menthol	0.4
Peppermint oil	1.0
	100.00%

This example will provide a clear bead the appearance of which may be varied in order to appeal to different sectors of the population. The refractive index of hydrated silica is similar to that of the matrix in which it is suspended.

EXAMPLE 4

<i>Component</i>	<i>% w/w</i>
Hot water	q. s.
Gelatine	8
Glycerine	40
Texapon OC-N	2

<i>Component</i>	<i>% w/w</i>
Synthecol CAB	4
V41 salt	2.6
Na Saccharin	0.2
Na Fluorophosphate	1.4
Sodium dihydrogen citrate	1
Menthol	0.8
Peppermint oil	2.0
	100.00%

355 Some people consider that the abrasive/dentifrice component of toothpaste, used to physically attack plaque, is not needed especially with use of electric toothbrushes. This option will delete the abrasive. Half-size (0.25 g) beads may be sufficient to fulfil the functions of toothpaste in which case 100 g of the above mixture is sufficient for about 400 beads. Each bead would be translucent because of deletion of an opaque dentifrice.

EXAMPLE 5

<i>Component</i>	<i>% w/w</i>
Hot water	q. s.
Gelatine	8
Glycerine	40
Texapon OC-N	2
Synthecol CAB	4
Na Saccharin	0.1
Anionic disinfectant eg Triclosan	0.01
Menthol	0.8
Peppermint oil	2.0
	100.00%

360 Quaternary ammonium compounds (such as benzalkonium chloride) are also effective disinfectants but would require a cationic detergent instead of the anionic sodium lauryl sulphate (Texapon OC-N) used here. The peppermint oil and menthol are retained for the subjective "clean" effect as well as to hide any taste from the active materials.

EXAMPLE 6

<i>Component</i>	<i>% w/w</i>
Poly ethylene glycol, (PEG) MW ca 8,000	50
Texapon OC-N	1
Synthecol CAB	2
V41 salt	1.5
Na Saccharin	0.1
Dicalcium phosphate Victor DF	45
Na Fluorophosphate	0.7
Peppermint oil No. 1	1
Menthol	0.4
Citric acid	0.4
	100.00%

365 This version provides dry, fully solid tablets, which may be pressed into individual beads each of about 0.25 g weight. The propylene glycol acts like a solid, waxy solvent yet is itself water-soluble. A gas-generating substance such as sodium bicarbonate may optionally be included in order to provide a gas-generating effect when the tablet is wetted by reacting with the citric acid.

EXAMPLE 7

<i>Component</i>	<i>% w/w</i>
Boiling water	32.1
(Note A) Agar	0.8
Glycerine	15
Texapon OC-N	1
Synthecol CAB	2
V41 salt	1.5
Na Saccharin	0.1
Dicalcium phosphate Victor DF	45
Na Fluorophosphate	0.7
(Note B) Peppermint oil No. 1	1
(Note B) Menthol	0.4
Citric acid	0.4
	100.00%

370 Note A: Agar was obtained from Coastal Biologicals, Auckland, New Zealand. The CAS number of agar is 9002-18-0.

Note A: Variations in the concentration of this agar were tested. Values of around 0.2% - 0.5% give beads which are too soft and friable. Above about 0.9% gives beads which are too hard and which have poor mouth feel - they do not break up easily when in use and they are difficult to
375 hold on the brush. Also, the quantity of agar used is preferably minimised for cost reasons.

Note B: Other flavouring and colouring agents were substituted in some samples, as for the (b) and the (c) version of Example 1.

Manufacture:

1. Add agar, glycerine, Texapon OC-N (wetting agent), Synthecol CAB , salt, and Na saccharin
380 to a jacketed vessel and mix.
2. Add boiling water q. s. and mix while raising the temperature to 95-100 deg C in order to fully dissolve the agar.
3. Add dicalcium phosphate and sodium fluorophosphate and mix to a smooth white liquid.
4. Let the temperature drop to 65 deg C while mixing.
- 385 5. Dissolve the menthol in peppermint oil.
6. Add the menthol/peppermint mix and the citric acid when the temperature is less than about 50 deg C and mix.

7. Pump mixture through a chilled 6.5 mm ID pipe onto a conveyer belt and cut into approximately 10 mm lengths. (200 items). (The mixture sets at about 35-40 deg C).

390 8. Pack into an airtight container.

RESULTS:

1. Appearance: crisp white gel with an oily surface. (Use of agar provides the result that the gel will not re-melt unless heated to well above the setting or gelling temperature).

2. pH of a 10% slurry in water = 5.95.

395 3. Dimensions: An about 6.5 mm diameter, 10 mm cylinder weighs about 0.5 grams.

It will be evident to one of skill that the method described above is capable of application on an industrial scale; whether carried out in batch mode or in a continuous mode. Reliance on temperature to cause setting is more convenient than reliance on for example addition of a chemical. It will also be evident to one of skill that a variety of ways to finally "cast" or otherwise shape each bead are available from various fields of industrial arts.

400 For example the mixture, while above its gelling temperature, may be dripped or extruded on to a cold belt, may be injected into a mould, smeared over a plate or belt having shaped depressions, or extruded from a shaped aperture, so that the mixture gels and assumes the shape in which it is constrained at the time. (A hot environment may follow to cause some surface dehydration). The inherent property of agar in which the re-liquefying temperature is well above the gelling temperature is useful for storage or carriage at elevated temperatures.

EXAMPLE 8

<i>Component</i>	<i>% w/w</i>
Hot water	q. s.
Alginic acid	4
Gelatine	4
Glycerine BP	25
Sodium bicarbonate	0.5
Sodium chloride (V41 salt)	1.3
Na saccharin	0.1
Dicalcium phosphate dihydrate	50
Na fluorophosphate	0.2
Sodium dihydrogen citrate	0.5
Peppermint oil	0.5
	100.00%

Notes:

This example illustrates use of a mixture of food grade structural gels. The resulting beads may be provided with a harder "shell" by dipping into a cold brine including calcium chloride, whereupon a calcium alginate layer is formed on the surface. Example 8 beads may exhibit an

adequate shelf life while minimising use of agar. Alternatively, or as well, the beads may include calcium ions, perhaps by partial substitution of the V41 salt towards the end of the manufacturing process (see example 1) so that the entire bead becomes more rigid as a result of formation of calcium alginate throughout.

USER TESTS

1. An objective of the user tests was to ensure that specific compositions were acceptable to the public. Tests were carried out in confidence and the participants had no knowledge of the composition of the beads under test.

2. The test research participants were a selected group of people with an age range of from 6 to 82 yrs. The following results were taken across different ages and palate preferences, the flavour issues are of little concern as these are in most cases easily rectified to suit without having undue effects on the stability of the formulae.

3. The children were not directly asked as to a preference of buds or paste, for fear of offering a leading question. It was considered better to just offer them to the children to try from time to time. The children took the offered product and went off to brush as usual, they did not appear to question the option or in any way refuse to brush or comment either way, almost as if they had accepted the change as a natural progression.

VARIATIONS

Tests of the above Examples have concentrated on two forms of long-chain gelling agent; gelatine and agar, in the first instance. Trials on alternatives and mixtures of alternatives, such as a mixture of agar and locust bean gum, or a mixture of gelatine and alginate are in progress. Carrageenan may be partially or completely substituted for the agar of Example 7.

Xanthan gum exhibits pseudoplasticity, that is, viscosity decreases as the shear strength increases. This effect may enhance the user perception of the beads breaking down in the mouth, if an xanthan component is used as a structural gel/gum.

A variation in the style of use of toothpaste was noted. Some people use a dry brushing action at the start then add water and reported that the beads are compatible with this procedure. Therefore the beads with an oral hygiene system (beads, container, and brushing means) could be used without water if necessary - saliva will flow as a result of the action.

COMMERCIAL ADVANTAGES

Advantages realised during manufacture of this dental hygiene system include:

1. A bead having no external wall as such is simpler to manufacture than one including a specific outer capsule layer (made of potato starch, gelatine, or the like) and is wholly

4. convertible into an oral or dental hygiene composition when broken up within the mouth by action of teeth and tongue, or with the aid of a toothbrush.

2. Solid beads are simpler to manufacture than toothpaste tubes filled with a semi-solid paste.
3. The processes use a fall of temperature to initiate setting; more convenient than use of an added material.

450 Inherent advantages of the beads of this invention include:

1. Convenience in storage, handling, and use; the material behaves as dry items until put into the mouth. The beads are easily stored, decanted, and dispensed.
2. Reduction in waste - no discarded toothpaste tubes, no capsule residue to spit out.
3. Each member of a family may use the flavour and type of toothpaste that they prefer which is an advantage for those trying to encourage their children to clean their teeth voluntarily.
4. Beads may be presented in many forms or styles, particularly including visual attractiveness, varieties in shape and colour, and hence added appeal to children. Children can pick a flavour or a shape, like a star for the evening.
5. There is an opportunity to mix flavours, especially for children, within the one pack.

- 460
6. A single dispenser may be shared, without hygiene / cross-infection problems, by groups of people (such as a family, or a school camp, scout camp, or military group).
 7. Tablets or beads of breath freshener, headache pills, or the like can be stored together with beads of encapsulated toothpaste. (This is particularly useful for a traveller).

Advantages to a user of the dental hygiene system of this invention include:

- 465
1. Beads of the invention are highly compatible with use of portable toothbrushes. Prior art for portable toothbrushes includes use of standard semi-liquid toothpastes which are difficult to handle and restrain.
 2. Beads comprise a version of toothpaste in a form likely to be attractive to users and especially to children. The invention provides conventional components of known toothpaste but in a different physical form.
 - 470 3. The invention is compatible with, and likely to enhance existing programmes of tooth care and dental hygiene, especially those for children, where the variety of beads and the control of the amount in each is likely to assist in voluntarily brushing the teeth.
 4. The oral hygiene system (beads, container, and brushing means) has an enhanced portability because a compact article provides all materials and tools required for cleaning the teeth and freshening the mouth (except water).
 - 475 5. The simplicity, self-contained nature and portability of the entire oral hygiene system, which

relies on these beads, could assist with third world oral hygiene development in addition to the reduction of cross infection from communicable diseases.

- 480 6. Apart from the emphasis on tooth hygiene, a rise in orally transmitted diseases (including meningitis, hepatitis, and recently tuberculosis) where kissing or shared drinking vessels may be involved in transmission leads to desirability of providing a cache of medicated beads within an oral hygiene system according to the invention.
- 485 7. The oral hygiene system is convenient for travelling people and those undertaking outdoor pursuits such as trampers, climbers, military personnel or the like in part because the weight and volume of an entire toothpaste tube is an unnecessary extra load and consumer of space.
- 490 8. Promotional toothbrushes as used by airlines and hotels for example are more conveniently manufactured and distributed together with this more easily handled toothpaste composition. Perhaps as few as 1 - 6 beads per pack need be supplied. Beads may be refilled from dispensers or convenient pocket packs.
9. Waste packaging materials such as toothpaste tubes are minimised, so reducing pollution and landfill.
- 495 10. Toothbrush design can be adapted for the storage of a number (perhaps only a small number) of beads within the handle, thereby resulting in a single object for a single function (cleaning the teeth).
11. Even the ubiquitous narrow plastic handled toothbrush can be made with a visible internal cavity and a removable, perhaps resilient resealable plug for accessing a bead as required - perhaps only in emergency.
- 500 12. A toothbrush having a solid, well-made handle with a cavity for containing beads can be made to use a replaceable brush end, and optionally also can be made with a cover for travelling. The cover may become part of the handle when in use, consequently reducing the bulk to be carried.

Finally, it will be understood that the scope of this invention as described and/or illustrated within this provisional specification is not limited to the illustrative embodiments described herein. Those skilled in the art will appreciate that various modifications, additions, and substitutions are possible without departing from the scope and spirit of the invention as set forth.

Carl Ernest Alexander and Francis William Grayson



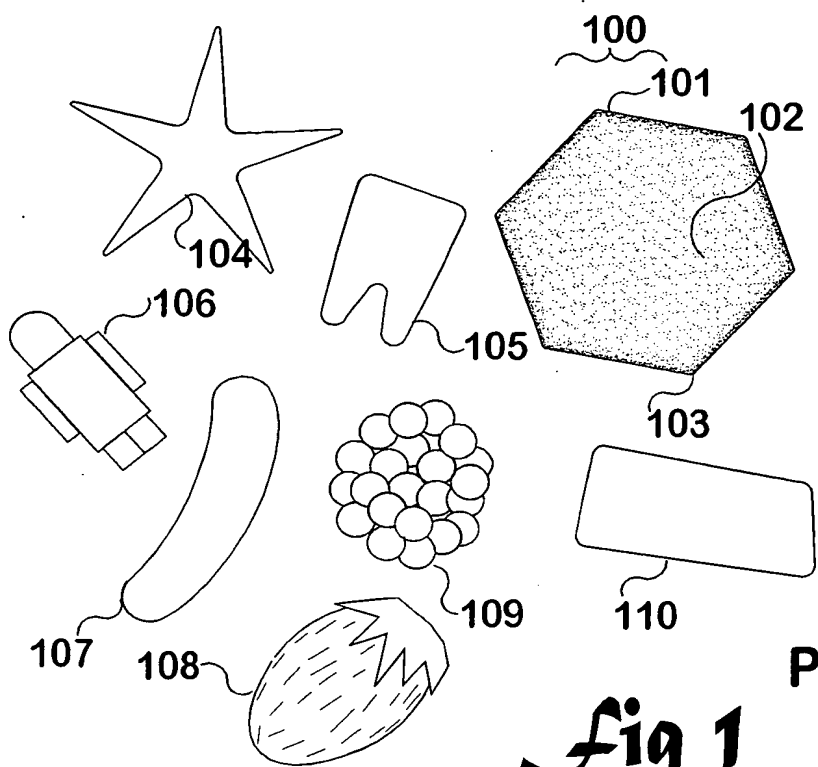
By their attorneys,

ENSOR AND ASSOCIATES.

ABSTRACT

This invention provides a component for an oral/dental hygiene system; a non-encapsulated single-use bead including enough food-grade structural gel (preferably agar) to make the bead a soft solid, yet allowing the bead to be disrupted in the mouth for use. Active bead ingredients are similar to those of existing toothpastes or oral cleansers/disinfectants.

515 Variations in colour and flavour make use of the beads attractive to children. Beads are highly compatible for use with portable or "pocket" toothbrushes especially those including one or more storage cavities (such as one for dental hygiene beads; the other holding oral hygiene beads, or medication necessary for daily or emergency use).



PRIOR ART

Fig 1

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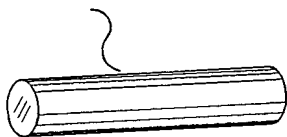
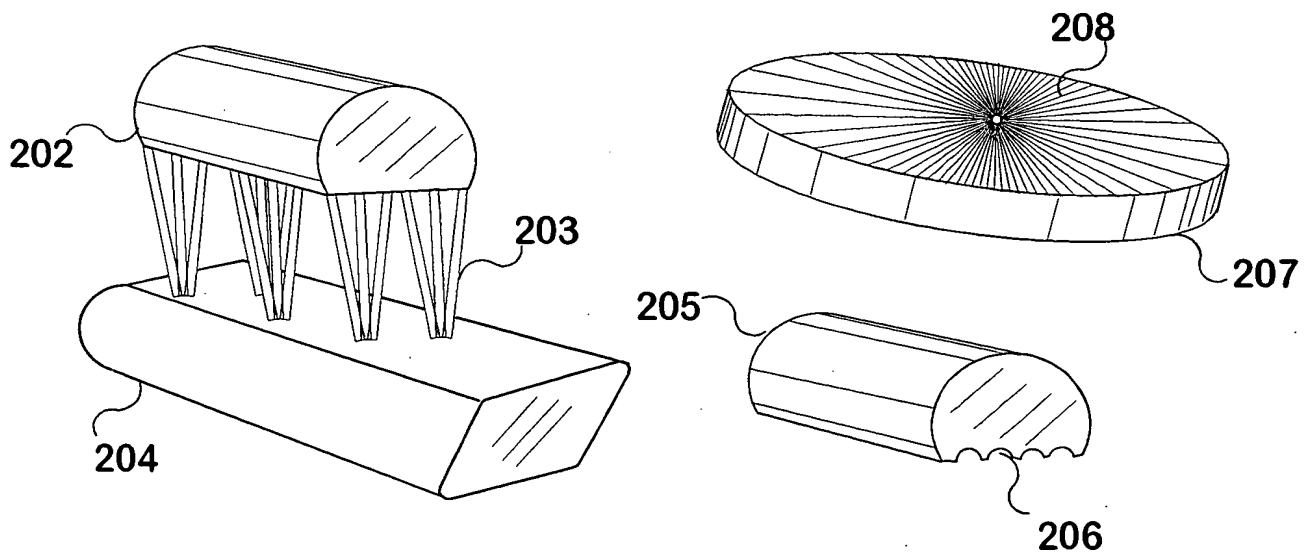


Fig 2



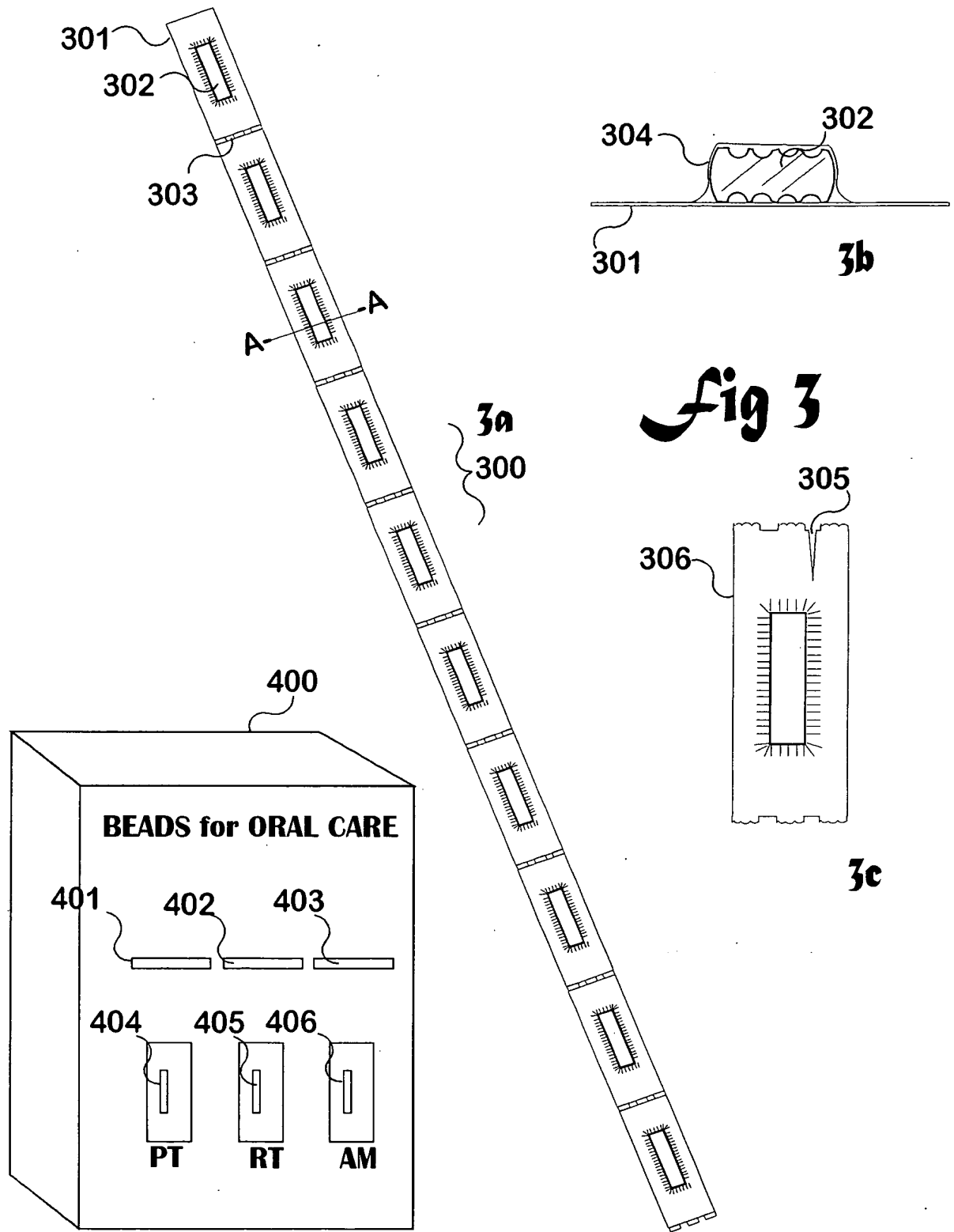


Fig 4

